

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 20-125 (LPS)
)	(CONSOLIDATED)
ARCHERDX, INC., ARCHERDX, LLC and)	
INVITAE CORP.)	REDACTED -- PUBLIC VERSION
)	
Defendants.)	

**NATERA, INC.'S LETTER BRIEF IN SUPPORT OF
NATERA, INC.'S MOTION TO COMPEL DISCOVERY**

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Dear Chief Judge Stark:

Pursuant to the Court's Oral Order (D.I. 223), Plaintiff Natera, Inc. ("Natera") respectfully requests that the Court compel Defendants, ArcherDX, Inc., ArcherDX LLC and Invitae Corp. (collectively, "Defendants") to: (1) provide 30(b)(6) and 30(b)(1) witnesses and dates in response to Natera's deposition notices and reach agreement on Natera's proposed dates for its witnesses; (2) supplement their responses to Interrogatory Nos. 2 and 10-11; and (3) produce documents to Request Nos. 8 and 9. Natera requests the Court to compel Thomas Jefferson University Hospital ("TJUH") to produce a witness for deposition.

I. Rule 30(b)(6) and 30(b)(1) Deposition Notices

Natera requests that the Court compel Defendants to provide dates and designations for its Rule 30(b)(6) and 30(b)(1) witnesses and reach agreement on dates Natera has provided for its witnesses by June 21 or within a shorter period of time. Defendants still have not designated a single witness for any of the topics in Natera's Rule 30(b)(6) deposition notice, have only offered a date for one of its eight noticed Rule 30(b)(1) witnesses, and have not confirmed any of the dates Natera has provided for seven of Defendants' noticed Rule 30(b)(6) and 30(b)(1) witnesses. (D.I. 218.) It has been a month since the parties noticed the Rule 30(b)(6) depositions and more than three weeks since the parties noticed Rule 30(b)(1) depositions – more than enough time to identify witnesses and propose deposition dates. Defendants' unilateral delay to provide this necessary discovery has prejudiced Natera and is in contravention of the Scheduling Order governing this case, which requires the parties to complete fact discovery by July 9. D.I. 60.

Natera maintains that depositions could be completed under the current case schedule. Nonetheless, on Monday, Natera sent to Defendants a reasonable proposal to complete depositions by August 20 along with minor adjustments to the expert report schedule that does not prejudice Natera in response to Defendants' Saturday evening proposal. Ex. 1. But Defendants still refuse to provide dates for most of their witnesses (on June 14, Defendants proposed a deposition date for *one* witness) or agree on Natera's proposed dates for its witnesses. *Id.* Even if Natera's modified schedule proposal is adopted, Natera requests that the Court order Defendants to begin depositions now and to conduct the majority of them in late June and July. Such relief is necessary so that Natera is not again prejudiced by a party not reasonably cooperating in the scheduling of depositions and Natera is not facing a jammed schedule in August to complete all depositions.

II. Interrogatory No. 2 / RFP No. 8 (Defendants' use of the Accused Products)

Interrogatory No. 2 seeks critical information related to Defendants' use of the Accused Products and corresponding RFP No. 8 seeks documents relating to use of the Accused Products in the United States, including in Defendants' CLIA-certified laboratories. In a supplemental response to Interrogatory No. 2 provided nine months after its original response, Defendants, for the first time, asserted that they "will not produce documents sufficient to show use by Archer of the accused products to the extent that the use falls under the protection of the Hatch-Waxman Safe Harbor, 35 U.S.C. § 271(e)(1)..." Ex. 2. Defendants' refusal is improper as such information is relevant to infringement, damages and injunctive relief and is within the scope of permissible discovery under Rule 26.

First, Natera requests that Defendants be ordered to produce documents and provide an interrogatory response that shows the Accused Products' uses and their purposes that may or may not be within the Safe Harbor. As this Court ruled last fall when denying Defendants' Rule 12(c) motion on the Safe Harbor, resolution of whether an infringing use is protected by the Section 271(e)(1) Safe Harbor is a *factual issue*. D.I. 59 at Tr. 22:2-25:8 (October 2, 2020); *see also* D.I. 27 at pp. 4-9 (Natera Rule 12(c) Opposition and authorities therein that Safe Harbor is a factual issue and context specific). Defendants' refusal to produce documents and provide a proper interrogatory response on such uses contravenes their Rule 26 obligations. Most importantly, it leaves Natera with no way to know whether such Accused Product uses are, or are not, legitimately protected under the Section 271(e)(1) Safe Harbor.

Defendants' refusal forecloses resolution of these factual disputes and violates the requirement that each of the accused activities must be evaluated separately to determine the applicability of the Safe Harbor. *See, e.g., Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) ("Each of the accused activities must be evaluated separately to determine whether the exemption applies."); *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1338-41 (Fed. Cir. 2019) (finding that certain batches of drug fell outside the safe harbor because they were not required by the FDA and were intended for commercial inventory). Effectively, Defendants' position usurps the role of the judicial fact finder on the issue Defendants bear the burden of proof. *Ventrassist Pty Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1286 (S.D. Fla. 2005). Natera requests that Defendants be ordered to provide the discovery *at once* that shows and describes the Accused Product uses and their purposes.

Second, Defendants' refusal to produce even the *number* of such so called "protected" uses denies additional proper discovery that is highly relevant to infringement and damages. Defendants have simply refused to produce any documents sufficient to show the number of such uses or suggest any other proposal other than a general description of the nature of uses. Natera requests that the Court further compel Defendants to produce responsive documents and information sufficient to show the number of such claimed exempt infringing uses.

III. Interrogatory Nos. 10 and 11 (Prosecution Laches and Unclean Hands)

Interrogatory Nos. 10 and 11 seek the legal and factual basis for Defendants' allegations that Natera's patent infringement claims are barred under the doctrine of prosecution laches and the doctrine of unclean hands. *See* Ex. 3. Natera requests that Defendants be compelled to provide a fulsome response at once.

In response to Interrogatory No. 10, Defendants provide no substantive response other than to incorporate the "Answer and Counterclaims (D.I. 21) in its entirety into this response." Ex. 3. at p. 23. Archer's Answer contains bald allegations that are devoid of the factual support for its allegations. *See* D.I. 21 at pp. 90-99 (which consists of only a recital of the prosecution history of the Asserted Patents). In response to Interrogatory No. 11, Defendants provide a cursory statement that "Natera filed the applications leading to the Asserted Patents shortly after one of its senior executives, Ms. Debra Giorda, left Natera, began working for Archer, gained access to confidential information relating to Archer's products in development, and then returned to Natera." Ex. 3. at pp. 23-24. But Defendants' response fails to provide the factual support for the allegations,

including for example, (i) the dates Ms. Giorda worked at Archer, (ii) the Archer confidential information, if any, that Ms. Giorda gained while working at Archer and how she accessed it, and (iii) why and how that information is relevant for an allegation of unclean hands. With fact discovery scheduled to close by July 9, Natera is prejudiced from not knowing the factual basis for Archer's serious allegations. Natera requests that the Court compel Defendants to supplement these interrogatories so that Natera can fairly conduct necessary fact and expert discovery to respond to these allegations, on which Defendants bear the burden of proof.

IV. RFP No. 9 (Design, Testing, Performance, and Sales of the Accused Products)

Natera requests the Court to compel Defendants to produce "customer" documents that Defendants had agreed to produce by April 30, 2021 under this Court's April 1 and 26 Orders. *See* D.I. 175 (Joint Status Report pursuant to the Court's April 1 verbal Orders) at pp. 6-7; D.I. 184 (April 26, 2021, Order adopting agreed upon April 30 production date). Defendants agreed to produce documents or communications sufficient to show for six Archer customers: (i) any agreements, contracts, statements of work, proposals, requests for proposals between Archer and the customer; (ii) instructions for use, product protocols, and/or product manuals provided to the customer including any testing or customization of any of the accused products for the customer and steps or process the customers perform with the accused products; and (iii) statements made by Archer comparing the accused products to products and services sold by Archer's competitors. *Id.*

Despite these representations and Order, Defendants only today produced what appear to be some of these documents (though Natera has not had time to evaluate prior to filing this letter brief whether the production is fully complete). *See* Ex. 4 (prior emails to Defendants highlighting the discovery deficiencies). This last minute production violates this Court's Order and Defendants' representations, and continues a pattern of withholding and necessitating judicial intervention on plainly relevant discovery. The urgency for these documents is further compounded by Archer's representations to its six customers (who Natera has also subpoenaed) that Natera should seek the requested documents directly from Archer because they are allegedly duplicative of documents Archer produced. Natera requests an Order that these documents all be produced at once, that a written representation be filed of compliance, and any other relief the Court deems appropriate, including fees for necessitating additional motion practice.

V. Thomas Jefferson University Hospital (TJUH) Deposition

Natera requests that the Court enforce Natera's January 4 subpoena on TJUH. Through a series of extension requests, the original TJUH counsel agreed to provide a witness and documents. Ex. 5. Now, Defendants' counsel is representing TJUH and refusing to provide a witness for deposition. Ex. 6. TJUH is a large hospital with almost 10,000 employees and is one of Archer's larger customers (based on information currently available to Natera). The deposition is relevant to Natera's indirect infringement and damage claims against Defendants. Nonetheless, Natera offered to consider a written declaration in lieu of deposition. TJUH, however, conditioned that declaration on Natera's agreement not to call a TJUH witness at trial, which was unacceptable to Natera, given that Natera was yet to receive a declaration and evaluate whether it was fulsome and responsive. Natera requests that the Court compel TJUH to produce a witness for deposition.

Respectfully,

/s/ Anthony D. Raucci

Anthony D. Raucci (#5948)

Enclosures

cc: All Counsel of Record (w/enc.) – By E-Mail